## NIH/OER/OPERA

[December 21, 2016]

## **REQUEST FOR JUST-IN-TIME INFORMATION**

## THIS IS NOT A NOTICE OF GRANT AWARD NOR SHOULD IT BE CONSTRUED AS AN INDICATOR OF POSSIBLE AWARD.

This is a standard notice and request for information from all principal investigators with grant applications receiving an impact score of 30 or less (regardless of the IC's payline) which reflects NIH's current tightened paylines and new Impact Scoring system. This notice is a request for Just-In-Time Information. NIH Institutes and Centers (ICs) have varying pay lines and funding strategies that determine which grants will be funded.

If a decision is made to fund this application, the assigned IC will need the following information PRIOR to making an award.

• **Current Other Support:** Provide active and pending support information for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes or gifts are not included. There is no form page for providing other support, although sample format pages are available at

http://grants.nih.gov/grants/funding/phs398/othersupport.doc and

http://grants.nih.gov/grants/funding/phs398/othersupport.pdf. Note that effort devoted to projects must be measured in person-months.

- For all senior/key personnel, provide details on how you would adjust any budgetary, scientific, or effort overlap if this application is funded.
- For Career Development Award applications, information on all active support for the candidate, sponsor(s), co-sponsor(s), and Senior/Key Personnel may be requested by the awarding component prior to award.
- Certifications:
  - IRB Approval: If the proposed project involves human subjects research, the certification date of IRB review and approval must be submitted. Pending or out-of-date approvals are not acceptable.
  - IACUC Approval: If the proposed project involves research with live vertebrate animals, the verification of the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable.
  - **Human Subjects Education:** If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted.
  - Human Embryonic Stem Cells (hESCs): If the proposed project involves hESCs and the

applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line(s) should be included.

- Institutional Certification for Human Genomic Data Sharing: If the proposed project involves a genomic data sharing plan for the generation of human genomic data, investigators must submit an Institutional Certification, or, in some cases, a Provisional Institutional Certification. Institutional certification forms and directions for completing them are available on the NIH GDS: http://gds.nih.gov/Institutional\_Certifications.html. This certification should be submitted as a "Genome Data Sharing Certification" in the eRA Commons Just-in-Time module.
- SBIR Funding Agreement: For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification described in Section 2.18 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://grants.nih.gov/grants/forms/manage\_a\_small\_business\_award.htm . This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.
- STTR Funding Agreement: For STTR applicants, provide only upon request the STTR Funding Agreement Certification described in Section 2.19 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://grants.nih.gov/grants/forms/manage\_a\_small\_business\_award.htm http://grants.nih.gov/grants/forms.htm#sbir. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.
- Other Information Requested by the Awarding IC: NIH IC's may also request additional Just-in-Time information on a case-by-case basis, such as revised budgets or changes to the human subjects or vertebrate animal sections of the application. These changes should be submitted as an "Other Upload" file in the eRA Commons Just-In-Time module.

Applicants must submit their information at least 60 days before the proposed project period start date. However, you should contact the IC for specific guidance. We understand that obtaining IRB and/or IACUC approval may take more than two weeks. Therefore, you may submit these approvals at the earliest date they are available.

All of the information must be submitted electronically using the Just-In-Time feature of the eRA Commons found in the Commons **Status** section. For information on the Commons see: <u>https://commons.era.nih.gov/commons/index.jsp</u>.

Timely submission of the requested information will enable NIH staff to expedite an award should an application be identified for funding. Institute staff will contact you if they have not received the requested information or if additional information is required. If you have any additional questions, please contact the assigned Grants Management Specialist. Contact information for these individuals can be found in Commons Status.

Please be reminded that this notice and request for information applies only to principal investigators with grant applications receiving an impact score of 40 or less (regardless of the IC's payline). For additional information on the Just-in-Time procedures, see section 2.5.1 of the NIH Grants Policy Statement.